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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/518,949	12/17/2004	Hugo Streekstra	BJS-4662-367	3538

23117	7590	11/29/2007
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EXAMINER	
LILLING, HERBERT J	

ART UNIT	PAPER NUMBER
1657	

MAIL DATE	DELIVERY MODE
11/29/2007	PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

## Office Action Summary

Application No.

10/518,949

Applicant(s)

STREEKSTRA ET AL.

Examiner

HERBERT J. LILLING

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 29 October 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☐ Claim(s) \_\_\_\_\_ is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

1. Receipt is acknowledged of an amendment filed October 29, 2007.
2. Claims 16-34 are pending in this application.  
Claims 1-15 have been cancelled.
3. The rejections as noted by paragraph 3 of the last office action dated April 30, 2007 have been withdrawn for the rejections based on first paragraph of 35 U.S.C. 112 in view of the persuasive arguments for:
  - a. Claims [1, 2 and 4-6 (cancelled)] and 16-33 and (b) claims 27-29 in combination with claims 31-33 under 35 U.S.C. 112, first paragraph, and c) for the persuasive reasons submitted for the microorganisms.
4. The rejection of the claims based on Suzuki et al has been withdrawn in view of the persuasive arguments.
5. However, claims 16-34 remain rejected under 35 U.S.C. 103(a) as obvious over Barclay et al US 5,882,703; Higashiyama et al., US 6,746,857; Kawashima et al., US 5,322,780 or Akimoto et al., US 5,128,250 in accordance with the following decisions regarding the obviousness (or lack thereof) of claimed inventions in light of the Supreme Court's recent decision in KSR International Co. v. Teleflex Inc (TFX). 82 USPQ2d 1385 (2007).

Consideration has been along the guidelines of The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

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1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

The reasoning includes the established Court of Appeals for the Federal Circuit standard that a claimed invention may be obvious if the examiner identifies a prior art teaching, suggestion, or motivation (TSM) to make it in this application which is employ a process for the production of ARA by controlling the rate of consumption of carbon source. However, the Guidelines explain that there is no requirement that patent examiners use the TSM approach in order to make a proper obviousness rejection. Furthermore, the Guidelines point out that **even if the TSM approach cannot be applied to a claimed invention, that invention may still be found obvious.**

The continued rejection of the claims which have been considered to be obviousness rejections that are supported by appropriate facts and reasoning, the Guidelines identify a number of rationales suggested by the Supreme Court in the KSR decision. For each rationale, the Guidelines explain the underlying factual findings, and provide guidance about how to reason from the facts to the legal conclusion of obviousness."

As indicated in the previous rejection

"Each of the references teaches the preparation of arachidonic acid by culturing a *Mortierella alpina* microorganism in the presence of glucose having a carbon source which includes glucose which is added to the fermentation vessel at a temperature within the scope of the claimed invention. The rate of addition is considered to be inherent within the scope of the claims or at least the method consumes one or more of the fats or lipids in preference to arachidonic acid or the rate is within the scope absent a showing to

the contrary. The percentage of AA is at least 40% as indicated in Example 1 Table 1 of Barclay et al.”

In addition, the following:

“If there are any differences with respect to the rate of addition, source or temperature, these differences would have been prima facie obvious in view of the disclosure of the references absent unexpected or unobvious process steps.”;

which differences as indicated above in view of the rationales suggested by the Supreme Court in the KSR decision which renders the claims prima facie obvious.

The present amended claim 16 recites the following:

“A process for the production of arachidonic acid (ARA), the process comprising culturing a micro-organism which is *Mortierella* in a culture medium inside a fermentation vessel, whereby at a stage which precedes the end of fermentation, of the carbon source is added at a rate below the rate of consumption of the carbon source by the micro-organisms.”

Each of the references still is considered to render the claims prima facie obvious in view of the claim language which only requires a first stage for the culturing a micro-organism from the genus *Mortierella* and a second stage which precedes the end of fermentation (EoF) adding [the-no antecedent basis] a carbon source is added at a rate below the rate of consumption of the carbon source by the microorganisms.

It would be prima facie obvious to one of ordinary skilled in the art, to add a carbon source during the initial stage which timewise is one minute or more minutes, several hours or 120 hours, that one would reasonably expect that adding any carbon source which would also include 0.5- 4 g/kg medium per hour, would increase the production of

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ARA until the end of fermentation. It is noted that the references do not disclose the specific rate of addition but the specification lacks patentable subject matter based on the comparison showings since the addition was only after 126 – 150 hours for each of the four examples.

The claims as presented in view of the specification lack patentable subject matter, which includes the comparative examples of Examples 1 and 2 vs, Examples 3 and 4. The examples lack suitable showings except from about 10 before EoF.

Based on the references and the lack of claimed patentable subject matter, in view of the Supreme Court Decision KSR International Co. v. Teleflex Inc (TFX) ., 82 USPQ2d 1385 (2007), this Examiner will not allow the instant claims

6. **No claim is allowed.**

7. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

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the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

8. Applicant may submit:

a-more persuasive reasons;

b-declaration(s);

c-amendments to the claims ;

d-pre-Appeal Brief;

e-go to the Board of Appeals.

f-if any further assistance is requested, please contact this Examiner.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Lilling whose telephone number is 571-272-0918 and Fax Number is **571-273-8300**. or SPE Jon Weber whose telephone number is 571-272-0925. Examiner can be reached Monday-Friday from about 7:30 A.M. to about 7:00 P.M. Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

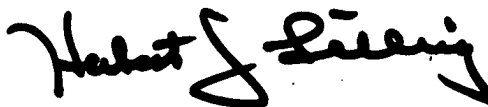
Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

H.J.Lilling: HJL

(571) 272-0918

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November 20, 2007



Dr. Herbert J. Lilling  
Primary Examiner  
Group 1600 Art Unit 1657